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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,742	03/03/2006	Benjamin Ross Herbert	60023150-0010	4559
26263 7590 07/10/2007 SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606-1080			EXAMINER TSAY, MARSHA M	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 07/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,742	HERBERT, BENJAMIN ROSS	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/08/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Group II, claims 19-23, in the reply filed on May 18, 2007 is acknowledged.

Claims 1-18, 24-26 have been withdrawn from further consideration by the Examiner because they are drawn to non-elected inventions. Claims 19-23 are currently under examination.

Priority: The benefit date is November 4, 2002, for the purpose of prior art.

Claim Objections

Claims 19, 21-22 are objected to because of the following informalities: in claim 19(a), line 3, the term "poteinaceous" should be corrected to "proteinaceous"; in claim 21, line 1, the term "claims" should be corrected to "claim", in line 3, the term "HPLC" needs to be defined in full; in claim 22, the substeps (iv) and (v) need to be corrected to (iii) and (iv) respectively, since there is no substep (iii) in claim 22. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is drawn to a method of solubilizing at least one proteinaceous macromolecule in a biological sample without inducing substantial acid hydrolysis. The term "substantial" is a relative term which renders the claim indefinite. The term "substantial" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further claim 19(i) recites incubating the biological sample in the presence of a reagent at a pH between about pH 1.0 and about 6.0. Since it is known in the art that a pH of 1.0 is strongly acidic, it is unclear how said biological sample can be solubilized without inducing substantial acid hydrolysis since it is believed that a pH of 1.0 is "substantially" acidic. Claim 20 is similarly rejected for the same reasons.

Claims 19(ii)(a) and claims 20(iii)(a) recite precipitating one or more proteins in the extract to thereby precipitate at least the solubilized proteinaceous macromolecules and resuspending the precipitated proteinaceous macromolecule. It is unclear how one or more proteins in the extract precipitates the solubilized proteinaceous macromolecule.

Claim 19(c) recites under conditions sufficient to resolve the proteinaceous macromolecule from other macromolecules present in the biological sample. It is unclear what sufficient conditions and what sufficient time are deemed to be sufficient. In claim 19(c) lines 4-5, the phrase "the biological sample" is confusing because it appears to refer to the "biological sample" recited in the preamble. The samples in 19(i), 19(ii)(a), and/or 19(ii)(b) are all more purified than the "biological sample" in the preamble. This phrase should be rewritten for clarification or deleted.

Claims 22-23 are included in this rejection because they are dependent on the above claims and fail to cure the defect.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by DeWitt et al.

(May 2002 Journal of Food Science 67(9): 3335-3341; IDS). DeWitt et al. teach protein extraction from beef heart using acid solubilization. DeWitt et al. teach comminuted beef heart was diluted with citric acid and homogenized with a polytron (p. 3336 col. 2; claims 19(i), 20(i)). The samples were acidified to pH 2.5 and centrifuged (p. 3336 col. 2; claims 19(i), 20(ii)). Protein from the supernatant was precipitated by decreasing acidity to the isoelectric point pH 5.5 and solubilized with 5% SDS for SDS-PAGE evaluation (p. 3336 col. 2; claims 19(a), 20(a)). DeWitt et al. further teach protein analysis by SDS-PAGE electrophoresis (p. 3337 col. 1; claim 21).

Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Sato et al. (1977 European Journal of Biochemistry 78: 557-567; IDS). Sato et al. teach two-dimensional polyacrylamide gel electrophoresis of membrane proteins of E. coli cells. Sato et al. teach E. coli cells were incubated with lysozyme and disrupted by sonication and centrifugation in order to

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prepare the membrane fractions (p. 558; claims 19(i), 20(i)). Sato et al. further teach that the some of the membrane fractions were solubilized by precipitation in 10% trichloroacetic acid, washed with 5% trichloroacetic acid and acetone, and then solubilized in lysis buffer (p. 559; claims 19(a), 20(a)). The lysis buffer contained 8M urea, 2% Triton X-100, 2% ampholines, and 2% mercaptoethanol to produce a standard pH range 4-6.5 (p. 559 col. 1-2; claims 19(i), 20(ii)). The proteins were analyzed by 2-D electrophoresis (p. 559 col. 2; claim 21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeWitt et al. (May 2002 Journal of Food Science 67(9): 3335-3341; IDS) in view of Wall (US 20030168585). The teachings of DeWitt et al. are outlined above. DeWitt et al. also teach that endogenous proteases (proteolytic enzymes) are present in bovine cardiac muscle. DeWitt et al. do not teach protein identification and/or analysis by mass spectroscopy.

Wall teaches a method of determining the purity of a sample comprising performing mass spectroscopy on a sample to create a mass spectrum, as well as treating the sample to proteolytic digestion prior to mass spectroscopic analysis (p. 1 [0012], p. 4 claims 1-5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of DeWitt et al. by adding the mass spectroscopic analysis

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step of Wall to the protein extraction and analysis step of DeWitt et al. (claims 22-23). One of ordinary skill would be motivated to use mass spectrometry to analyze the protein of DeWitt et al. because said method is a standard analytical tool used in proteomics that can supplement SDS-PAGE in protein analysis.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 3, 2007

M. Monshi
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER